UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 2 1 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

The Honorable David Vitter
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Senator Vitter:

Thank you for your June 25, 2014, letter regarding the U.S. Environmental Protection Agency's final risk assessment on Trichloroethylene (TCE), developed as part of the agency's Toxic Substances Control Act (TSCA) Work Plan effort.

The EPA's final TCE risk assessment, released on June 25, 2014, exemplifies the sound, appropriate use of the best available scientific information to characterize risks to consumers and workers. It is supported by a robust health effects database, covering human health endpoints including cancers to the kidney, liver, and immune system (non-Hodgkin lymphoma); and noncancer effects on the liver, kidney, nervous system, immune system, and reproductive and developmental systems. This database has undergone extensive review by several independent, expert scientific bodies. Your letter expresses concern over one study, concerning one toxicological endpoint, used in the assessment: Johnson *et al.* (2003), which evaluated developmental toxicological effects of TCE exposure on the fetus. Limitations and questions about the Johnson *et al.* study have been noted in the EPA toxicity assessments. The EPA has judged that the weight of the evidence supports a conclusion that TCE may cause cardiac fetal defects. This conclusion was supported by the agency's Science Advisory Board in 2011 on the draft Integrated Risk Information System (IRIS) assessment, and more recently by the 2013 peer review of the Office of Pollution Prevention and Toxics (OPPT) TCE risk assessment and the EPA's systematic evaluation of the TCE developmental toxicity endpoint.

The EPA's draft TSCA risk assessment on TCE did not include the Johnson study. However, the independent expert panel that reviewed the draft indicated that the assessment should include the Johnson study. The peer review of the OPPT TCE risk assessment, including drafting of the charge to the reviewers, was conducted following Office of Management and Budget and EPA guidelines. The charge included eleven questions to elicit advice on the structure of the risk assessment document, the exposure assessment, the hazard assessment, and the assessment's approach to characterizing risk. The charge question related to the Johnson study, "Please comment on whether the 2011 IRIS assessment's PBPK-derived inhalation values from oral studies should be used in the final OPPT risk assessment," was developed through an intra-agency process and was endorsed by the agency's senior leadership. As is the EPA's practice, the TCE charge was released for public comment along with the draft risk assessment. Aspects of the charge were revised based on public comments. However, we received no comments on the specific charge question referenced in your letter.

The EPA also took an extra step of conducting a new systematic evaluation (enclosed) of the developmental toxicity literature for TCE, including any new literature that was found in response to peer review recommendations. The new evaluation supports the inclusion of Johnson *et al.* in the OPPT risk assessment. In addition, some concerns about the design of the Johnson *et al.* study were recently addressed in an Errata published in 2014. OPPT's final TCE risk assessment will not, nor should it, end the generation of new scientific information on TCE. That said, it is clear that we have sufficient information to assess the risks to consumers and workers from certain TCE products. Note that fetal cardiac defects are only one of the adverse health effects that the final OPPT TCE risk assessment concluded were potential effects from the use of TCE in certain products.

You have requested documents related to three issues: (1) the conduct of the independent, expert scientific peer review of the draft OPPT TCE risk assessment; (2) a 2001 publication co-authored by Dr. Stanley Barone; and (3) the lateral move of Dr. Stanley Barone into the position of Deputy Director, Risk Assessment Division, Office of Pollution Prevention and Toxics. I have enclosed documents responsive to your request.

The 2001 study referenced in your letter, of which Dr. Barone was one of eight co-authors from several government and industry organizations, was part of a multidisciplinary project to evaluate the long-term health effects of several different pesticides across multiple forms of toxicity. Based on post-publication comments, at their own initiative the authors convened an independent expert group to review the study findings. Based on that review, in 2004 the authors published a letter to the journal that published the 2001 study, withdrawing one aspect of their study findings—conclusions on neuropathology—but retaining all the other (neurobehavioral, immunological, and general toxicity) findings in the paper. That the authors responded to questions by convening a panel, modifying their findings, and transparently announcing those modifications in the open literature, reflects a high degree of scientific integrity.

Finally, you ask about Dr. Barone's move from Chief of the Risk Assessment Division's Science Support Branch, to Deputy Director of the Risk Assessment Division. This was a noncompetitive lateral move, with no change in pay grade or salary for Dr. Barone. No one was promoted or demoted as a result of this move.

Again, thank you for your letter and I hope the information provided is helpful to you. If you have any further questions, please contact me or your staff may contact Mr. Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at (202) 566-2753 or Kaiser.Sven-Erik@epa.gov.

Sincerely,

James J. Jones
Assistant Administrator

Enclosures